

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Solomon S. Steiner, Rodney J. Woods, and Joseph W. Sulner

Serial No.: 10/719,734 Art Unit: 1616

Filed: November 21, 2003 Examiner: Alstrum Acevedo, James Henry

For: *PURIFICATION AND STABILIZATION OF PEPTIDE AND PROTEIN
PHARMACEUTICAL AGENTS*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit a Supplemental Information Disclosure Statement, including one (1) page of Form PTO-1449 and copies of the two (2) documents cited therein.

This Supplemental Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(d) after a Notice of Appeal. The Commissioner is hereby authorized to charge a fee of \$180.00 to Deposit Account No. 50-3129, representing the fee required under 37 C.F.R. §1.17(p). It is believed that no additional fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-3129.

Certification Under 37 C.F.R. § 1.97(e)(2)

Each item of information listed below this certification in this Supplemental Information Disclosure Statement was not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, each item listed below was not known to any individual designated in § 1.56(c) more than three months prior to the filing of this Supplemental Information Disclosure Statement.

Publications

JONES, et al., "An investigation of the pulmonary absorption of insulin in the rat", *Third European Congress of Biopharmaceutics and Pharmacokinetics*, 1987.

SAKR, "A new approach for insulin delivery via the pulmonary route: design and pharmacokinetics in non-diabetic rabbits", *International Journal of Pharmaceutics*, 86:1-7 (1992).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

/ Rivka D. Monheit /

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